



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0155]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Quantitative Research on Front of Package Labeling on Packaged Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on a proposed collection of information. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice invites comments on an information collection associated with a study entitled “Quantitative Research on Front of Package Labeling on Packaged Foods.”

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0155 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Quantitative Research on Front of Package Labeling on Packaged Foods

OMB Control Number 0910-NEW

The United States continues to face an epidemic of diet-related chronic diseases, many of which are experienced disproportionately by racial and ethnic minority groups, those with lower socioeconomic status, and those living in rural areas.¹ To help address this problem, FDA has continued to prioritize its nutrition activities² to help empower consumers with nutrition information to make healthier choices more easily and encourage industry innovation by

¹ <https://www.cdc.gov/obesity/index.html>.

² <https://www.fda.gov/food/food-labeling-nutrition/fdas-nutrition-initiatives>.

providing flexibility to facilitate the production of healthier foods. FDA is focused on: (1) creating a healthier food supply for all; (2) establishing a healthy start to set the foundation for a long, healthy life; and (3) empowering consumers through informative labeling and tailored education.³

FDA is exploring the development of a front of package system to help consumers interpret the nutrient information on food products. Front of Package (FOP) labeling is intended to complement the Nutrition Facts label by giving consumers a simple aid to provide additional context for making healthy food selections. As part of our food-labeling efforts, we are exploring the establishment of a standardized, science-based FOP scheme that helps consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy eating pattern.

The increased attention in recent years to FOP, and the experiences of countries that have adopted FOP labeling suggests that FOP labeling may aid nutrition comprehension and the ability to make healthier choices, especially for those with lower nutrition literacy. FOP schemes adopted in countries throughout the world include both mandatory and voluntary labeling schemes and include non-interpretative, interpretative, nutrient specific, and summary schemes.

In 2022, FDA conducted a review of the literature on FOP nutrition-related labels and conducted a set of focus groups to test FOP concepts and draft FOP schemes (see Docket No. FDA-2023-N-0155 for the literature review). These focus group results provided insights into the varying ways that consumers interpret FOP nutrition information. As part of our efforts to promote public health, we intend to conduct an experimental study, informed by results of the focus group testing, to further explore consumer responses to various FOP schemes. In the experimental study, we will test a smaller subset of FOP schemes from the focus group testing, with additional variations informed by, among other things, focus group results (see

³ <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>.

https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202008-0910-021&icID=253321 for information about FDA’s front-of-pack focus groups, including graphic FOP schemes tested). The study will be a controlled, randomized experiment that will use a 15-minute web-based questionnaire to collect information from 3,000 U.S. adult members of an online consumer panel maintained by a contractor. The sample will be balanced to reflect the U.S. Census on gender, education, age, and ethnicity/race. A measure of nutrition literacy will also be used to balance the sample to ensure a variety of literacy levels for each condition.

Conditions for the study will be: (1) a set of draft FOP schemes, including “no-scheme” controls; (2) three types of mock food products (i.e., a breakfast cereal, a frozen meal, and a canned soup); and (3) a “no-information” condition where no explanation of the FOP scheme is provided. Each participant will be randomly assigned to a condition, which will include viewing a label image and responding to various measures of the label’s effectiveness. Some assignments may include making a choice between two label images. Product perceptions (e.g., healthfulness and contribution to a healthy diet), label perceptions (e.g., believability, trustworthiness, and effects perceptions), and purchase/choice questions will constitute the measures of response in the experiment. The instrument will also collect information from participants about their history of purchasing or consuming similar products, nutrition knowledge, dietary interests, motivation regarding label use, health status, and demographic characteristics.

The studies are part of our continuing effort to help enable consumers to make informed dietary choices and construct healthful diets. We intend to use the results to inform our continued exploration of an FOP labeling scheme. We will not use the results to develop population estimates.

Description of Respondents: Respondents to this collection of information include members of the general public.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Experiment Pretest 1	180	1	180	0.25 (15 minutes)	45
Experiment Pretest 2	25	1	25	0.25 (15 minutes)	6
Experiment	3,000	1	3,000	0.25 (15 minutes)	750
Total					801

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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